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INTER-SPINOUS PROCESS IMPLANT AND METHOD WITH DEFORMABLE SPACER

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Claim of Priority

[0001] This application claims priority to United States Provisional Patent Application entitled INTER-SPINOUS PROCESS IMPLANT AND METHOD WITH DEFORMABLE SPACER, filed September 18, 2001, Serial No. 60/323,467 and is a continuation-in-part of U.S. Patent Application Serial No. 09/799,215 filed on March 5, 2001,entitled SPINAL IMPLANTS, INSERTION INSTRUMENTS, AND METHOD OF USE, which is a continuation-in-part of U.S. Patent Application Serial No. 09/473,173 filed on December 28, 1999, entitled SPINE DISTRACTION IMPLANT, now U.S. Patent No. 6,235,030 issued on May 22, 2001, which is a continuation of U.S. Patent Application Serial No. 09/179,570 filed on October 27, 1998, entitled SPINE DISTRACTION IMPLANT, now U.S. Patent No. 6,048,342 issued on April 11, 2000, which is a continuation-in-part of U.S. Patent Application No. 09/474,037 filed on December 28, 1999 and entitled SPINE DISTRACTION IMPLANT, now U.S. Patent No. 6,190,387, issued February 20, 2001, which is a continuation of U.S. Patent Application Serial No. 09/175,645 filed on October 20, 1998, entitled SPINE

DISTRACTION IMPLANT, now U.S. Patent No. 6,068,630 issued on May 30, 2000. All of the above are incorporated herein by reference.

Field of the Invention

[0002] The present invention is generally related to an implantable device adapted to distract the spinous process of adjacent vertebrae in order to alleviate the back pain caused by, for example, spinal stenosis and other ailments.

Background of the Invention

[0003] The vertebral column is a bio-mechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The bio-mechanical functions of the spine include (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk and arms to the pelvis and legs, (2) complex physiological motion between these parts and (3) protection of the spinal cord and the nerve roots.

[0004] As the present society ages, it is anticipated that there will be an increase in adverse spinal conditions which are characteristic of older people. By way of example, with aging comes increases in spinal stenosis (including but not limited to central canal and lateral stenosis), the thickening of the bones which make up the spinal column, and the facet arthropathy. Spinal stenosis is characterized by a reduction in the available space for the passage of blood vessels and nerves. Pain associated with such stenosis can be relieved by

medication and/or surgery. Of course, it desirable to eliminate the need for major surgery for all individuals and in particular for the elderly.

[0005] In addition, there are a variety of other ailments that can cause back pain in patients of all ages. For these ailments it is also desirable to eliminate such pain without major surgery.

[0006] Accordingly, there needs to be developed implants for alleviating such conditions which are minimally invasive, can be tolerated by patients of all ages and in particular the elderly, and can be performed preferably on an out patient basis.

Summary of the Invention

[0007] The present invention is directed to providing a minimally invasive implant for alleviating discomfort associated with the spinal column.

[0008] In one aspect of the present invention, the implant reduces and/or eliminates pain by relieving the pressure and restrictions on the aforementioned blood vessels and nerves. Such alleviation of pressure is accomplished by an implant which distracts the spinous processes in order to alleviate the problems caused by spinal stenosis, facet arthropathy and other spinal ailments. While the implant particularly addresses the needs of the elderly, embodiments of the invention can be used with individuals of all ages and sizes where distraction of the spinous processes and/or the maintenance of a spacing between the spinous processes would be beneficial.

[0009] Another aspect of the present invention includes an implant with a first support and a second support, having a compressible medium between the first and second support. The compressible medium preferably progressively limits the motion of the adjacent spinous process. The first and second support have a saddle for engaging each spinous process.

[0010] Yet another aspect of an embodiment of the present invention is a spacer adapted to be compressed in reaction to forces from a spinous process placed upon the spacer. The spacer has a compressible medium that provides resistance against compression. Such a flexible spacer provides an individual with a larger range of motion.

[0011] It is still another aspect of an embodiment of the present invention to include a compressible spacer which prevents wear debris.

[0012] Other implants and embodiments within the spirit and scope of the invention can be used to distract the spinous processes, to maintain the distance between the spinous processes and/or to increase the volume of the spinal canal, thereby alleviating restrictions on vessels and nerves associated therewith, and/or pain.

Brief Description of the Drawings

[0013] Figures 1a-1g; Fig. 1a is an assembly view of an embodiment of the invention; Fig. 1b is a side view of the embodiment of the invention of Fig. 1a including a spacer, a main body and a first wing; Fig. 1c is a plane view of the embodiment of the invention in Fig. 1b; Fig. 1d is a side view illustrating the second wing of the embodiment of

the invention in Fig. 1a; Fig. 1e is a plane view of the second wing of an embodiment of the invention of Fig. 1a; Fig. 1f is an end view of the spacer of the embodiment of the invention of Fig. 1a; Fig. 1g is a cut-away view illustrating the spacer of the embodiment of the invention of Fig. 1a.

[0014] Figure 2 is a perspective view of still another embodiment of the spacer of the invention;

[0015] Figure 3 is a perspective view of yet another embodiment of the spacer of the invention;

[0016] Figure 4 is a perspective view of still another embodiment of the spacer of the invention;

[0017] Figures 5a-5b; Figure 5a is a perspective view of yet another embodiment of the spacer of the invention; Figure 5b is an end view of the embodiment of the spacer illustrated in Figure 5a;

[0018] Figures 6a-6c; Figure 6a is a perspective view of yet another embodiment of the spacer of the invention; Figure 6b is a perspective view of the first outer shell of the spacer illustrated in Figure 6a; Figure 6c is an end view of the embodiment of the spacer shown in Figure 6a filled with a deformable or compressible material;

[0019] Figure 7 is a perspective view of yet another embodiment of the spacer of the invention;

[0020] Figures 8a-8b are perspective views of still other embodiments of the spacer of the invention; and

[0021] Figures 9a-9b; Fig. 9a is a perspective view of another embodiment of the present invention; Fig. 9b is a cut-away view of the embodiment of the invention illustrated in Fig. 9a.

Detailed Description of the Invention

[0022] An embodiment of the implant **100** is depicted in Figs. 1a, 1b and 1c. This implant includes the first wing **104** and sleeve **116** and a lead-in and distraction guide **110**. This embodiment further includes, as required, a second wing **132** as depicted in Figs. 1d and 1e. As can be seen in Fig. 1a, a central body **102** extends from the first wing **104**. Also, as can be seen in Figs. 1a and 1b, the guide **110** in this particular embodiment is pointed in order to allow the implant to be inserted between, and if necessary distract, adjacent spinous processes.

[0023] Additionally, As can be seen in Figs. 1a, 1f and 1g, the sleeve **116** is preferably cylindrical, and oval or elliptical in shape in cross-section. It is to be understood that sleeve **116** can have other shapes as described throughout the specification and be within the spirit and scope of the invention. Sleeve **116** includes a central bore **119** which extends the length of sleeve **116**. The sleeve **116** is received over the central body **102** of the implant **100** and can rotate thereon about the central body **102**. In these embodiments, the spacer **116** can preferably have minor and major dimensions as follows:

Minor Dimension (116a)	Major Dimension (116b)
6 mm	10 mm
8 mm	10.75 mm
12 mm	14 mm
6 mm	12.5 mm
8 mm	12.5 mm
10 mm	12.5 mm

[0024] In another preferred embodiment, the spacer **116** has a cross-section with a major dimension and a minor dimension and the major dimension is greater than the minor dimension and less than about two times the minor dimension.

[0025] It is to be understood that the sleeve can be comprised of biologically acceptable material such as titanium or stainless steel. Additionally, it can be comprised of super-elastic material such as an alloy of nickel and titanium. Other structural and material variations for the sleeve are described below.

[0026] The advantage of the use of the sleeve **116** as depicted in the embodiment of Figs. 1a is that the sleeve can be rotated and repositioned with respect to the first wing **104**, in the embodiment, in order to more optimally position the implant **100** between spinous processes. It is to be understood that the cortical bone or the outer shell of the spinous processes is stronger at an anterior position adjacent to the vertebral bodies of the vertebra that at a posterior position distally located from the vertebral bodies. Accordingly, there is some advantage of having the implant **100** placed as close to the vertebral bodies as is possible. In order to facilitate this and to accommodate the anatomical form of the

bone structures, as the implant is inserted between the vertebral bodies and urged toward the vertebral bodies, the sleeve **116** can be rotated relative to the wings, such as wing **104**, so that the sleeve is optimally positioned between the spinous processes, and the wing **104** is optimally positioned relative to the spinous processes. Without this capability, depending on the anatomical form of the bones, it is possible for the wings to become somewhat less than optimally positioned relative to the spinous processes.

[0027] As required, the implant **100** can also include a second wing **132** which fits over the guide **110** and is preferably secured by a bolt through apparatus **134** of second wing **132** to the threaded bore **112** located in guide **110**. As implanted, the first wing **104** is located next to the adjacent first side of the spinous processes and the second wing **132** is located adjacent to second side of the same spinous processes.

[0028] Referring now to Figures 2-8, various embodiments of spacers adapted for placing between the first wing **104** and the second wing **132** are shown. The preferred material for the various spacers described below is titanium in combination with a deformable material such as silicone. It is within the scope of the present invention to manufacture the spacers from other biologically acceptable material such as, by way of example only, stainless steel or an alloy of nickle and titanium along with another deformable material such as another deformable polymer.

[0029] Turning now to Figure 2, the spacer **200** includes an outer shell **202**. The outer shell **202** is integrally formed with the center shaft **206** by two support columns **204**. The center shaft has a bore **208** extending through. Each support column **204** extends

substantially perpendicular from the center shaft **206**. Between the outer shell **202** and the center shaft **206**, a cavity **205** is created.

[0030] The shape of the outer shell **202** as shown in Figure 2 is elliptical in shape. It is within the scope of the invention that the outer shell **202** may comprise other shapes such as, but not limited to, a cylindrical or egg shape. Regardless of the shape, the outer shell **202** is not continuous in this preferred embodiment. One half of the outer shell **202** extends from the end of one support column **204a** and around the center shaft **206** until the outer shell **202** almost reaches the second support column **204b**. The second half of the outer shell **202** is the same as the first half, and in this case both halves extend in a clockwise direction. Since each half of the outer shell **202** extends from a different support column **204**, two slots **210a** and **210b** are created. Both slots **210a,b** extend along the length of the spacer **200**. The slots **210** function to lower the rigidity of the outer shell **202** so that the outer shell **202** is more flexible and functions as a cantilever spring. The smallest diameter of the space (circular or elliptical) can preferably range from 6 mm. to 11 mm. The thickness of the outer shell can preferably be 2 mm. The spacer can have other dimensions as identified previously.

[0031] Preferably, a compressible substance **207** is placed into the cavities **205a,b** located between the outer shell **202** and the center shaft **206**. The compressible substance **207** provides resistance against the outer shell **202** traveling towards the center shaft **206**. As previously mentioned, the compressible substance in this embodiment is preferably silicone. It is within the scope of the invention that the compressible substance **207** may

comprise another medium such as, but not limited to, urethane-coated silicone and/or co-formed with silicone so that the urethane will not be attacked by the body, or another ultra-high molecular weight polymer. Another preferred material is polycarbonate-urethane, a thermoplastic elastomer formed as the reaction product of a hydroxl terminated polycarbonate, an aromatic diisocyanate, and a low molecular weightglycol used as a chain extender. A preferred polycarbonate glycol intermediate, poly (1,6-hexyl 1,2-ethyl carbonate) diol, PHECD, is the condensation product of 1,6-hexanediol with cyclic ethylene carbonate. The polycarbonate macroglycol is reacted with aromatic isocyanate, 4, 4'-methylene bisphenyl diisocyanate (MDI), and chain extended with 1, 4-butanediol. This material is preferable used at a hardness of 55 durometer. This material, as well as the other materials, can be used in the other embodiments of the invention.

[0032] The compressible medium preferably has a graduated stiffness to help gradually distribute the load when a spinous processes places a force upon the outer shell **202**. For example, the hardness of the silicone can be the lowest where the silicone contacts the outer shell **202**, and the hardness of the silicone can be the highest where the silicone contacts the center shaft **206**. Alternatively, the silicone can have a higher hardness in the center of the silicone located between the outer shell **202** and the center shaft **206**.

[0033] The compressible medium **207** fills the cavity between the outer shell **202** and the center shaft **206** and is flush with the outer shell **202**. When the spacer **200** is inserted between adjacent spinous processes, the outer shell **202** protects the compressible substance (e.g., silicone) from directly contacting the spinous processes because the slots

210 are along the side of the spacer **200**. Therefore, the deformable material **207** does contact the spinous processes and wear debris is reduced or eliminated.

[0034] It is to be understood that for this and also in the embodiments in Figures 3, 5a and 5b, the embodiment can be constructed without a compressible material, with the outer shell solely providing the flexibility of the spacer. It is also to be understood that the embodiments shown in Figures 3 - 8 can have the dimensions and be made of the materials similar to those of Figure 2. It is additionally to be understood that the metal components of any of the embodiments hereof can be comprised of a suitable plastic or composite material including fibers for strength.

[0035] Now referring to Figure 3, the spacer **300** has an outer shell **302** and a center shaft **306**. The center shaft **306** has a bore **308** extending through. The center shaft **306** is connected with the outer shell **302** by two support columns **304a,b**, with each support column **304a,b** located on opposite sides of the center shaft **306**. Similar to the embodiment of the present invention as illustrated in Figure 2, the outer shell **302** is elliptical, yet may comprise other shapes such as , but not limited to, a cylindrical or egg shape.

[0036] The outer shell **302** has two slots **310a,b**. The slots **310a,b** extend through the wall of the outer shell **302** to form a rectangular-like opening. It is within the scope of the invention for the spacer **300** to have more than two slots **310** and with different shapes. The slots **310a,b** are used to make the outer shell **302** more flexible. It is preferred that the slots **310a,b** are located on the sides of the spacer **300** so that none of the slots **310a,b** contact a spinous process.

[0037] Between the outer shell **302** and the center shaft **306** are two cavities **305a,b**. These cavities are separated by the support columns **304a,b**. The two cavities created between the outer shell **302** and the center shaft **306** preferably have a compressible substance therein. As previously mentioned, the compressible substance is preferably silicone. To improve the load distribution upon the outer shell **302** and ease the load on the spinous processes, the silicone can have a graduated stiffness. For example, the hardness of the silicone can be the lowest where the outer shell **302** contacts the silicone, and the hardness of the silicone can be the highest where the center shaft **306** and the support column **304** contacts the silicone. Alternatively, the silicone can have a higher hardness in the center of the silicone riding between the outer shell **302** and the center shaft **306**.

[0038] The silicone is placed between the outer shell **302** and the center shaft **306** so that the silicone extends into the slots **310** and is flush with the outer shell **302**. Since the spinous processes do not directly contact the silicone, this embodiment of the present invention also helps prevent wear debris.

[0039] Referring now to Figure 4, yet another embodiment of the present invention includes spacer **400**. The spacer **400** has an outer shell **402** and a center shaft **406.** The center shaft **406** has a bore **408** extending through. The spacer **400** has two openings **410a,b** that are substantially along the top **111** and bottom **113** portions of the outer shell **402**. Between the outer shell **402** and the center shaft **406**, cavities **405a,b** are created which connects the two openings **410a,b**.

[0040] Similar to the previous embodiments, a compressible medium such as silicone is placed into the cavity **405a,b** and openings **410a,b** until the silicone becomes flush with the outer shell **402**. Preferably, the silicone also has a graduated stiffness. For example, the hardness of the silicone can be the lowest where it is flush with the outer shell **402**, and can be the highest where the silicone contacts the center shaft **406**. Unlike the previous embodiments, the exposed silicone will directly contact the spinous processes.

[0041] Referring now to Figures 5a-5b, another embodiment of the invention is spacer **500**. The spacer **500** has an outer shell **502** and a center shaft **506**. The outer shell **502** forms a "C"-like shape. The center shaft **506** has a bore **508** extending through. The center shaft **506** is attached to the outer shell **502** by a support **504**. The support **504** is substantially horizontal extending from the vertical center of the "C" to the middle of the open end **509**. The outer shell **502** defines two slots **510a,b** along the length of the open end **509**. Both slots **510a, b** are defined by the space between the support **504** and each end portion of the outer shell **502**. Since the outer shell **502** is fixed at one end only, the outer shell **502** functions like a cantilever-type spring. The outer shell **502** is shown as elliptical in shape. It is within the scope of the present invention that the spacer **500** may comprise other shapes such as, but not limited to, a cylindrical or egg shape.

[0042] The support **504** has preferably at least two protrusions such as protrusions selected from protrusions **512a,b,c,d**. For example, the spacer **500** in Figures 5a,b has four protrusions **512a,b,c,d**. Each protrusion **512a,b,c,d** extends substantially and preferably perpendicular in this embodiment from the support **504** towards the inner surface of the

outer shell **502**. While the spacer **500** is in a non-compressed state, there is a gap between each protrusion **512a,b,c,d** and the outer shell **502**. When the spacer **500** is compressed, the protrusions **512a,b,c,d** function to restrict the deflection of the outer shell **502**. When a spinous process exerts a force upon the outer shell **502**, the outer shell **502** will deflect toward the center shaft **506** until the outer shell **502** contacts the protrusion **512a,b,c,d**. Essentially, the protrusions **512a,b,c,d,** function as a stop mechanism preventing the outer shell **502** from deflecting too much, and thus limiting the motion of the spinous processes.

[0043] Similar to the previous embodiments, cavities **505a,b** are formed between the center shaft **506** and the outer shell **502.** A compressible substance such as silicone is placed within the cavity **505**. It is preferable that the silicone have a graduated stiffness to help distribute the load placed upon the outer shell **502**. For example, the hardness of the silicone can be the lowest where the silicone contacts the inner surface of the outer shell **502**, and the hardness of the silicone can be the highest where the silicone contacts the center support shaft **506**, and the support **504** and the protrusions **512a,b,c,d**. Alternatively, the silicone can have a higher hardness in the center of the silicone rising between the outer shell **502** and the center shaft **506**.

[0044] The silicone fills the cavities **505a,b** until the silicone is flush with the outer shell **502**. When the spacer **500** is inserted between adjacent spinous processes, the top and bottom portions **514, 516** of the spacer **500** contact the spinous process. Therefore, the silicone will not directly contact the spinous processes which aids in the prevention of wear debris.

[0045] Referring now to Figures 6a-6c, another embodiment of the present invention is spacer **600**. The spacer **600** has a first outer shell **602** and a second outer shell **603**. The first outer shell **602** has at least two support elements **604a,b**. Each support element **604a,b** has a bore **605a,b** extending therethrough. The support elements **604a,b** are located substantially at either end of the first outer shell **602** along a single horizontal axis. The bores **605a,b** are oval in a preferred embodiment. This shape allows the spacer **600** to move relative to the central shaft or axis (Figure 1) upon which the spacer is mounted. The second outer shell **603** has a single support element **606**, located substantially in the center of the second outer shell **603** and along the same horizontal axis as the two support elements **604a,b**. The support element **606** also has a bore extending through which is similar to bore **605**. Support element **606** is located between support element **604a,b** in Fig.6a. A central shaft **612** (shaft **102** in Fig. 1c) is placed through the support elements **604a,b**, **606** to form a hinge-type connection between the first outer shell **602** and the second outer shell **603** (see Figure 6a). The hinge-type connection allows the first outer shell **602** and the second outer shell **603** to move independently of each other.

[0046] When the first outer shell **602** and the second outer shell **603** are connected by shaft **612**, slots **610a,b** are created along the side edges of the spacer **600**. Two cavities **614a,b** are also created, defined by the hinge-type connection between the first outer shell **602** and the second outer shell **603**. Similar to the previous embodiments, a compressible substance (e.g., silicone) can fill each cavity and extend into the slots **610a,b** until the silicone is flush with the first outer shell **602** and the second outer shell **603**. Additionally, it is

preferred that the silicone have a graduate hardness similar to the previous embodiments. In one embodiment, the hardness of the silicone can be the highest along view line A-A, and can be the lowest where the silicone contacts the first and second outer shell **602, 603**. Alternatively, the silicone can have the highest hardness where it contacts the support elements **604a,b, 606**, and can have the lowest hardness where the silicone fills the slots **610a,b**.

[0047] When the spacer **600** is inserted between adjacent spinous process, only the top and bottom portions **616, 618** of the spacer **600** will directly contact each spinous process. Therefore, the first outer shell **602** and the second outer shell **603** prevent direct contact between the silicone and the spinous process. Accordingly, the spacer **600** helps prevent wear debris from being formed.

[0048] Now referring to Figure 7, still yet another embodiment of the present invention is spacer **700**. Spacer **700** includes preferably a component in the shape of an elliptical or oval or cylindrical spool **710**. Alternatively, the component **700** can be formed for method or suitable plastic material or composites including, by way of example only, fibers for strength. The spacer **700** has a center shaft **702** with a bore **708** extending through . As in other embodiments the bore **708** can be, by way of example only, circular, oval or elliptical. A first end **704** and a second end **706** are integrally formed with the center shaft **702** in this preferred embodiment. Both the first end **704** and the second end **706** extend outward from the center shaft **702** and form a circular rim around each end of the center shaft **702**. It is within the scope of the present invention for the first end **704** and

second end **706** to comprise other shapes such as, but not limited to, elliptical, circular, oval or egg-shaped.

[0049] A compressible medium **712** surrounds the center shaft **702**. As previously mentioned, the compressible substance is preferably silicone. The silicone extends out from the center shaft **702** until it is flush with the outer rim of both the first end **704** and the second end **706**. With the silicone around the center shaft **702**, the spacer **700** will look like an elliptical cylinder in this embodiment. The spacer **700** does not have an outer shell surrounding the silicone. When the spacer **700** is inserted between adjacent spinous process, the silicone will directly contact the spinous process. A preferred embodiment of the spacer **700** will have silicone with a graduated stiffness to help distribute the load placed upon the spacer **700**. For example, the hardness of the silicone can be the lowest at the outermost surface that contacts the spinous process, and the hardness of the silicone can be the highest where the silicone surrounds and contacts the center shaft **702**. Alternatively the hardness can be greater where the silicone contacts the spinous process and then less hard adjacent to the center shaft **702**.

[0050] Now turning to Figure 8a, another embodiment of the present invention is spacer **800**. The spacer **800** has an outer shell **802** which can be metallic or plastic. The outer shell **802** is preferably elliptical in shape. It is within the scope of the present invention that the outer shell **802** can be a shape such as, but not limited to, a cylindrical or egg shape. Regardless of the shape, the outer shell **802** is open on both ends **808**, **810**.

[0051] A compressible substance **804** is placed within the outer shell **802** and is flush with both ends **808, 810** of the outer shell **802**. A bore **806** extends through the compressible substance **804**. If desired the bore can be defined by a metallic or plastic sleeve held on the compressible substance **804**. Similar to the previous embodiments, the compressible substance **804** is preferably silicone. A preferred embodiment of the spacer **800** has silicone with a graduated stiffness. In an embodiment, the hardness of the silicone can be the highest at the bore **806**, and the hardness of the silicone can be the lowest where the silicone contacts the inner surface of the outer shell **802**. Alternatively, the hardness of the silicone can be the highest adjacent shell and lowest about bore **806**.

[0052] When the spacer **800** is inserted between adjacent spinous processes, only the top and bottom portions **812, 814** will directly contact each spinous process. Therefore, the outer shell **802** prevents direct contact between the silicone and the spinous processes. Accordingly, the spacer **800** helps prevent wear debris from being formed.

[0053] By way of example only, the thickness of the outer shell can be about 0.010 inches with the hardness of the compressible medium being about 50 durometer. By way of example only, the outer shell can be about 0.010 inches with the hardness of the compressible medium being about 70 durometer.

[0054] It is also to be understood that the spacer **800** can include any of the compressible medium **804** discussed herein and/or compatible with the body, with a bore hole provided therethrough. That is to say that the outer shell **802** can be eliminated in this embodiment. Preferably the spacer is comprised of silicone, however, other materials are

within the spirit and scope of the invention. Fig. 8b depicts an egg-shaped spacer **800'** with a bore **809'**. The spacer **800'** is comprised of a compressible medium.

[0055] Referring now to Figs. 9a-9b, the interspinous process device on implant **900** has a first support **902** and a second support **904**. The first support **902** and the second support **904** directly contact the spinous process and can be made of a suitable metal or a suitable plastic. Both the first support **902** and the second support **904** have a contour **903**. The contour **903** allows the device **900** to be contoured to and to engage each spinous process so, preferably, that the device **900** does not move laterally. Each contour **903** includes a concave portion **920** and upstanding ridges **922, 924**. It is to be understood that the ridges can be higher than shown in Fig. 9a in order to define a deeper contour. Additionally, ridges **924**, especially when higher, of supports **903, 904** together can define a first wing and ridges **922**, especially when higher, of support **903, 904** define a second wing. Such wings can function in much the same way as the wings described in other embodiments of the invention.

[0056] During the method of implanting device **900**, both spinous processes are exposed using appropriate surgical techniques, and thereafter the device **900** is positioned so that the saddles **903** of both the first support **902** and the second support **904** engage the respective spinous process. The concave shape of the saddle **903** distributes the forces between the saddle **903** and the respective spinous process. This ensures that the bone is not reabsorbed due to the placement of the device **900** and that the structural integrity of the bone is maintained.

[0057] Referring now to Figure 9b, the first support **902** has a female receiving mechanism **906** and the second support **904** has a male engaging mechanism **908**. The width of the female receiving mechanism **906** and the male engaging mechanism **908** are substantially similar. The female receiving mechanism **906** further has an alignment column **905** to assist in the movement of the supports **902**, **904** relative to each other.

[0058] The first support **902** and the second support **904** are interlocked so that the first support **902** and the second support **904** cannot be independently separated. The first support **902** has a ledge **907** that extends around the inner circumference of the first support **902**. Similarly, the second support **904** has a ledge **909** extending around the circumference of the male engaging mechanism **908**. If the first support **902** and the second support **904** travel in opposite directions, the ledges **907** and **909** will eventually engage and prevent the first support **902** and the second support **904** from separating. Preventing the first support **902** and the second support **904** from separating also contains the compressible medium **910**, as described below, within the device **900**.

[0059] Placed within the female receiving mechanism **906** is a compressible medium **910**. As previously mentioned, the compressible medium **910** provides resistance, limiting the possible range of motion of the spinous process. By way of example only, the compressible medium **910** can be silicone. It is within the scope of the present invention that the compressible medium can include, by way of example only, a spring mechanism, a synthetic gel or a hydrogel. The compressible or deformable material can also include material which offers, for example, increased resistance to compression the more the

material is compressed. For example, as compression and deformation occur, the material can offer a steady resistive force or a resistance force that increases, either linearly or non-linearly, the more the implant is compressed.

[0060] With respect to an embodiment with a graduated stiffness, the hardness of the silicone can be the lowest where the first support **902** contacts the silicone, and the hardness of the silicone **910** can be the highest where the second support **904** contacts the silicone. Alternatively, the silicone can have a higher hardness in the center of the silicone riding between the supports **902**, **904**.

[0061] In this and with the other embodiments, the medium **910** can also be designed to vary resistance to movement according to the speed or rate of deformation. For example, when an individual leans back slowly, the adjacent spinous processes place a force onto the first support **902** and the second support **904**. With slow backward bending the force is small and gradual until the limit of compression of the material is reached. However, if the individual attempts a rapid activity that can result in a severe first compression of the device **900**, the medium **910** can offer higher stiffness, preventing the spinous processes from making excessive motion and causing pain.

[0062] Preferably, the height of the device **900** is slightly larger than the undistracted distance between the adjacent spinous processes. When the device **900** is then inserted between the spinous process, the contours **903** will press against each spinous process and assist to keep the device **900** in place. During a daily routine, an individual will perform functions that will translate into vertical movement of each spinous process. It is important

that the individual be able to retain some of his normal range of motion. To retain a normal range of motion, the device **900** can preferably be compressed when the spinous processes place a force upon the first support **902** and the second support **904**. Thus, when the device **900** is in a normal state the outer peripheral edge **930, 932** of first and second support **902, 904** respectively do not contact each other. However, ridges **930, 932** act as a limit to the amount device **900** can be compressed. Such an arrangement reduces potential resorption of the bone adjacent to the implant and to more gradually limit extension or backward bending of the spinal column.

[0063] The embodiment of this implant as well as the several other implants described herein act to limit extension. These implants, however, do not inhibit the flexion of the spinal column when the spinal column is bent forward.

[0064] The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and their equivalence.